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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/391,762	09/08/1999	KEVIN WEADOCK	498-36-RES	9047
23869	7590	05/03/2005	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			PREBILIC, PAUL B	
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			3738	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/391,762

Applicant(s)

WEADOCK ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7 and 9-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 9-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Regarding the April 14, 2005 amendment, claims 21-27 and 29-30 appear to have improper status identifiers because these claims were "new" in the October 25, 2004 amendment. The claims have been acted upon by Applicant is reminded of the proper use of the status identifiers, which would be "previously presented", in this situation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17, 18, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 18 are indefinite because they now contradict claim 13 that requires "a biodegradable composition having an acidic pH" contained in the pores. For this reason, it appears that Applicants are claiming two states of the invention at the same time.

Claim 28 contradicts base claim 13 that requires an acidic solution, yet the present claims attempts to claim a pH-adjusted solution. For this reason, it is unclear which of these two products are being set forth such that claim scope is considered indefinite.

Claims 1-4, 7, and 9-31 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein*,

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Inc., 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue, which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that Applicants previously surrendered during the prosecution of the application.

Accordingly, the narrow scope of the claims in the patent was not an error within the scope of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of a reissue application.

Present claims 1-4, 7, and 9-31 are improper for a reissue application because they attempt to recapture subject matter surrendered in order to overcome a prior art rejection. Specifically, during the pendency of the patented file 08/289,790, the language "filled with fluid which solidifies and is crosslinked to form" and "said material being insoluble at a pH of about 7.4" was added in order to overcome a prior art rejection; see the Examiner's Answer dated March 12, 2002 under the heading "Issue 1" on pages 8 to 11, which is incorporated herein by reference. Therefore, it is improper to attempt to recapture this subject matter via claims 1-4, 7, and 9-31 in the present reissue application.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, and 21-25 are rejected under 35 U.S.C. 102(b) as anticipated by Kaehler et al (journal article entitled "Precoating Substrate and Surface Configuration . . .") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kaehler et al (journal article entitled "Precoating Substrate and Surface Configuration . . .") alone. The following is paraphrased from the Board of Appeals decision rendered July 21, 2003, the rejection of claim 13 on page 8 of the decision. Kaehler describes a vascular graft which comprises a body of PTFE having a structure of spaced-apart nodes interconnected by fibrils having pores present between the fibrils and nodes. The vascular grafts used in Kaehler are reinforced (see Kaehler, page 536, left hand column, "Graft material") which are also described in the '114 patent as being e-PTFE on column 1, lines 56-63. The vascular grafts of Kaehler contain the nodes and fibril structure claimed as seen from a complete reading of Kaehler; see, for example, the paragraph bridging the two columns on page 537. The claims require that the implantable member of e-PTFE contains a biodegradable composition of natural origin in its pores. On page 536, Kaehler teaches forcing type I and III collagen through the graft repeatedly until it was almost impossible to force any more through; see page 536,

first full paragraph. This collagen is the same as the "solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores" because it is collagen that is pH adjusted outside the pores (see *supra*) and then forced through the pores. Even though a different method is used, the same product results because pH adjusted collagen ends up in the pores of the same substrate as claimed; see MPEP 2113, which is incorporated herein by reference.

Alternatively, since a different method is used to make the product, one may reason that a different product results. However, the Examiner asserts that any difference is only slight such that the claimed invention is at least obvious in view of Kaehler alone. For this reason, the Examiner the claimed product would have been considered at least obvious to an ordinary artisan in the art.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaehler (journal article entitled "Precoating Substrate . . . ") in view of Hoffman, Jr. et al (US 5,197,977). Kaehler meets or renders obvious the claim language as explained *supra* but fails to disclose the use of a pharmacological agent as claimed. However, Hoffman teaches that it was known to use pharmacological agents in similar grafts within the art; see the paragraph bridging columns 5 and 6. Therefore, it would have been considered *prima facie* obvious to an ordinary artisan to include a pharmacological agent in the Kaehler implant for the same reasons that Hoffman teaches doing the same.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaehler (journal article entitled "Precoating Substrate . . . ") in view of Tran et al

(article entitled "Plasma Modification. . ."). Kaehler meets or renders obvious the claim invention as explained *supra*, but fails to teach modifying the substrate to enhance its hydrophilic character (claim 11) by subjecting the polytetrafluoroethylene to plasma deposition (claim 12). However, Tran also describes polytetrafluoroethylene grafts, which are coating with collagen, and which have been pretreated to make them more hydrophilic by plasma deposition; see page 374 and page 379 including Table III. Therefore, it would have been considered *prima facie* obvious to an ordinary artisan to pretreat the graft of Kaehler to make it hydrophilic via plasma deposition in order to render the graft more receptive to collagen impregnation as taught by Tran.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaehler et al (journal article entitled "Precoating Substrate . . .") in view of Alonso (US 5,037,377). Kaehler meets or renders obvious the claim language as explained *supra*, but fails to disclose the pH of the phosphate buffer as claimed. However, Alonso teaches the phosphate buffers having pH's of 7.4 were known to the same art; see column 3, lines 31-41. Therefore, it is the Examiner's position that it would have been considered *prima facie* obvious to an ordinary artisan to use a 7.4 pH phosphate buffer for the same reasons that Alonso uses the same.

Claims 13-18 and 29-31 are rejected under 35 U.S.C. 102(b) as anticipated by Kaehler (journal article entitled "Precoating Substrate . . .") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kodama et al (US 5,028,597) in view of Kaehler (journal article entitled "Precoating Substrate . . .") or Hoffman, Jr. et al (US 5,197,977). Kodama discloses impregnating or coating an expanded PTFE graft with collagen to

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render it antithrombogenic and biocompatible; see the abstract, column 2, lines 65-68, column 4, lines 28-38, and Examples 2 and 5. Since the pores of the PTFE substrate are open on the surface of the graft, the Examiner reasons that the pores would inherently be at least partially filled with "a biodegradable composition having an acidic pH" in the form of collagen; see particularly column 4, lines 21-28 and lines 50-60. The Examiner reasons that collagen is "capable of forming a precipitate that substantially fills said pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment" because the it is the same material as that disclosed and claimed by the Applicants.

Alternatively, it is not clear that impregnation of collagen is within the pores as claimed because it is not explicitly disclosed as such. However, both Kaehler and Hoffman teach that is was known to impregnate collagen throughout the pores of the same or similar type substrate by forcing or massaging a solution thereof therethrough. For this reason, the Examiner asserts that it would have been at least obvious to impregnate the collagen of Kodama so that it is within the pores to a greater extent so as to make the graft thereof blood tight and for the same reasons that Kaehler or Hoffman do the same.

Regarding claims 17 and 18, since the limitations of these claims apparently contradict base claim 13, the Examiner asserts that claim 13 controls and that the claim language is fully met when given the claim 13 interpretation.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama, Hoffman, and Kaehler as applied to claims 13-18 and 29-31 above, and

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further in view of Hoffman, Jr. et al (US 5,197,977). Kodama meets or renders obvious the claim language as explained *supra* but fails to disclose the use of a pharmacological agent as claimed. However, Hoffman teaches that it was known to use pharmacological agents in similar grafts within the art; see the paragraph bridging columns 5 and 6.

Therefore, it would have been considered *prima facie* obvious to an ordinary artisan to include a pharmacological agent in the Kodama implant for the same reasons that Hoffman teaches doing the same.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama, Hoffman, and Kaehler as applied to claims 13-18 and 29-31 above, and further in view of Alonso (US 5,037,377). Kodama meets or renders obvious the claim language as explained *supra*, but fails to disclose the pH of the phosphate buffer as claimed. However, Alonso teaches the phosphate buffers having pH's of 7.4 were known to the same art; see column 3, lines 31-41. Therefore, it is the Examiner's position that it would have been considered *prima fascia* obvious to an ordinary artisan to use a 7.4 pH phosphate buffer for the same reasons that Alonso uses the same.

Response to Arguments

Applicant's arguments with respect to the present claims have been considered but are moot in view of the new ground(s) of rejection. The Examiner has further explained and modified the rejections such that the arguments set forth in the response are considered moot or at least addressed by the new explanation provided in the rejections.

In response to the claim 28 Section 112, second paragraph rejection traversal that claim 13 has been amended to overcome the indefiniteness, the Examiner maintains that the Applicants are still attempting to claim two states of the invention in claim 28. For this reason, the claim scope is considered indefinite because it is not clear which of the two pH's are being required by the claim.

With regard to the 35 USC 251 rejection traversal that the claims are not recapturing surrendered subject matter because there are narrower than the originally filed claims, the Examiner asserts Applicants' standard for recapture is not proper. Specifically, if Applicants made amendments to overcome prior art rejections, as is the situation here, it is not proper to leave out these limitations in reissue claims; see MPEP 1412.02, which is incorporated herein by reference.

With regard to the traversals of the prior art rejections, the Examiner agreed with Applicants' arguments to some extent and have modified the rejection in order to address Applicants' concerns. For this reason, Applicants' arguments are considered to be rendered *moot* in light of the new grounds of rejection.

Response to Amendment

The declaration under 37 CFR 1.132 filed April 14, 2005 is insufficient to overcome the rejection of claims 1-4, 7, and 21-25 based upon Kaehler as set forth in the last Office action because:

(1) The declaration constitutes opinion evidence and has no actual proof. For this reason, it is of little probative value; see MPEP 716.01(c)(III), which is incorporated herein by reference.

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(2) The claims are at least partly rejected under Section 102 so the declaration has no direct effect on this rejection. However, it is noted that declarant's attempt to argue that Kaehler does not have the claimed structure and does not anticipate or render obvious the claim language. Declarant's arguments, however, are considered unpersuasive.

(3) The declarant argues that Kaehler does not disclose collagen within the pores of the substrate, but does not offer any actual proof. Furthermore, these arguments directly contradict the actual language of Kaehler that states that "the collagen solution was forced through the graft interstices"; see page 536, second column, first full paragraph. Since the pores are open, even a coating of the open pores would result in some collagen within the pores. Furthermore, since the collagen was forced through the pores to the extent that the pores or interstices become clogged, it is not seen how this process does not result any collagen within the pores as argued.

(4) The pores of a expanded PTFE are open at the surface and extend below the surface. Furthermore, the claim language does not require that the pores are completely filled. For this reasons, the argument that the pores are contain no collagen is considered unpersuasive since a solution would inherently fill the interstices of a graft to some extent.

(5) Declarant's arguments are not commensurate with the claims' scope that do not require that the pores be substantially or completely filled; see paragraph 13 of the declaration. For these reasons, the declarant's arguments are considered unpersuasive.

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Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738